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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,438	08/01/2003	Robert H. Oakley	033072-044	4547

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,438	OAKLEY ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/1/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 35 are pending in the instant application.

The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 2 of the instant application, for example, is presented on three separate panels. The three sheets of drawings which are labeled " Figure 2" in the instant specification should be renumbered "Figures 2A, 2B and 2C". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3) Claims 1 to 35 are rejected under 35 U.S.C. 103(a) as being obvious over the Bohn et al. patent (6,528,271 B1) in view of the Gurevich et al. (J. Biol. Chem. 270(2):720-731, 13 Jan. 1995) and Hodgson (BIO/TECHNOLOGY 10:973-977, 10 Sep. 1992) publications. The text on lines 34 to 41 in column 2 and lines 7 to 37 in column 5 of the Bohn et al. patent described a method of identifying compounds that potentiate receptor agonist activity by inhibiting the binding of β-arrestin to phosphorylated receptor. The Gurevich et al. publication shows that it was well known in the art at the time of the Bohn et al. patent that the response of G protein-coupled receptors (GPCRs) like that of Bohn et al. to continuous agonist activation diminished with time as a consequence of receptor desensitization. Gurevich et al. explains that one mechanism of GPCR desensitization involved the phosphorylation of agonist activated receptor by a G protein-coupled receptor kinase (GRK) followed by the binding of an arrestin protein to that phosphorylated receptor. The Gurevich et al. publication is being relied upon because it shows that Bohn et al. knew that compounds identified by the method

described therein "potentiated" receptor agonist activity by inhibiting agonist-induced receptor desensitization and, thereby, effectively increased the activity of an agonist when administered therewith. The method of Bohn et al. is only distinguished from the claimed method in that it lacks a comparative step employing a different receptor.

The Hodgson publication is a review article explaining the particular strategies employed in the art for the identification of potentially useful pharmacological compounds based upon the ability of those compounds to agonize or antagonize specific receptor proteins. The text on page 977 therein states that "[f]irst you need all the receptors that are the plus targets-so that you are providing all the sites to which an active compound might bind" "[a]nd then you need all the minus targets-so that you can design away any negative effects". Because it was known that "GPCRs have important roles in mediating fundamental physiological processes such as vision, olfaction, cardiovascular function, and pain perception" as disclosed in column 1 of the Bohn et al. patent, one of ordinary skill would have been motivated not only to identify compounds that inhibit agonist desensitization of a target receptor for the purpose of enhancing agonist activity on that receptor, that artisan would have been further motivated to include other GPCRs in such an assay to identify those compounds that **only** inhibit the desensitization of a target receptor or set of target receptors, such as the opioid receptor of Bohn et al. for use in controlling pain, without inhibiting agonist desensitization of those GPCRs involved in mediating other fundamental physiological processes such as vision, olfaction, cardiovascular function, etc. An artisan of ordinary skill in the art of receptor biology would have found it *prima facie* obvious to have

included "all the minus targets" in the assay of Bohn et al. for the purpose of identifying compounds that specifically inhibit the agonist desensitization of a target GPCR without affecting the agonist desensitization of other physiologically relevant receptors such as the adrenergic, serotonin, metabotropic glutamate and dopamine receptors at the time that the instant invention was made.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1600